

K962780

AUG 29 1996

510(k) Summary

- a.1. Diagnostic Hybrids, Inc.
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Athens, OH 45701
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Attn: J.L. Brown
Date of Preparation: July 12, 1996
- a.2. Trade Name: **FreshCells™**
Classification Name: Cells, Animal and Human, Cultured.
- a.3. A predicate device is that of BioWhittaker, marketed as cell cultures, Appendix II, p.19 of this 510(k) Notification.
- a.4. The subject device provides HEP-2 cells as nearly confluent monolayers ready for use upon receipt after a short pre-incubation period.
- a.5. Intended Use: Cell cultures to be used for specific virus isolation and identification. The subject of this 510(k) Notification, the cell line, HEP-2, is susceptible to and can be used in the isolation and confirmation of the following viruses from clinical samples:

| | |
|-------------|---------------|
| Adenovirus | Parainfluenza |
| HSV | Poliovirus |
| Coxsackie B | RSV |
| Measles | |

- a.6. A comparison of Technological Characteristics:

| <u>Characteristics</u> | <u>Predicate Device</u> | <u>Subject Device</u> |
|--|--|---------------------------|
| Source of Cell Line. | ATCC or another approved supplier. | Same as predicate device. |
| Provided as nearly confluent monolayers. | Cells are provided routinely as nearly confluent monolayers. | Same as predicate device. |
| Intended Use. | Isolation & Confirmation of specific viruses. | Same as predicate device. |

- b.1. The non-clinical tests consist of those used to characterize the product such as appearance, growth characteristics, sterility, isoenzyme analysis and virus susceptibility.
- b.2. Not applicable.
- b.3. Not applicable.